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non replicative recombinant adenoviral vector comprises a heterologous polynucleotide sequence encoding a polypeptide, which polynucleotide sequence is inserted into an entirely deleted E1 region of said non replicative recombinant adenoviral vector and is under the control of a promoter recognized by polymerases of muscle cells and wherein said polypeptide is expressed in said muscle cells[, associated with] and (ii) a pharmaceutically acceptable carrier.

Please add the following new claims:

--17. (New) The composition according to Claim 15, wherein said polynucleotide sequence encodes a polypeptide having thrombolytic properties.--

--18. (New) The composition according to Claim 15, wherein said polynucleotide sequence encodes a polypeptide which is all or part of a dystrophin gene product.--

--19. (New) The method according to Claim 15, wherein said polynucleotide sequence encodes a polypeptide which is a  $\beta$ -galactosidase gene product.--

*C2*  
--20. (New) The composition according to Claim 15, wherein said promoter is a promoter contained in the Long Terminal Repeat of a Rous Sarcoma Virus.--

--21. (New) The composition according to Claim 15, wherein said promoter is an adenoviral E1A early region promoter.--

#### REMARKS

Entry of the foregoing and favorable reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. Section 1.112, and in light of the remarks which follow, are respectfully requested.

By the present amendment, Claims 10 to 14 and 16 have been canceled solely to expedite the prosecution of this application and not to acquiesce to the Examiner's rejection. Applicants

reserve their rights to file a Divisional application directed to the canceled subject matter. Claim 15 has been amended to further clarify the present invention. Claims 17 to 21 have been added. Applicants submit that no new matter has been added via this amendment. Claims 15, 17-21 are currently pending. Applicants submit the pending claims are supported by the specification.

**Rejection of Claims 15 and 16 Under 35 U.S.C. § 102(b)**

Turning now to the Official Action, Claims 15 and 16 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Rosenfeld et al. Claim 16 has been canceled. As far as this rejection may pertain to the newly amended Claim 15, this rejection is respectfully traversed.

Rosenfeld et al teach an adenoviral vector that has a portion of the E3 region and a portion of the viral E1A coding region deleted. The portion of the viral E1A coding region contains an insert of an  $\alpha$ 1AT expression cassette, which contains an E1A enhancer region. This adenoviral vector was effective in transferring the  $\alpha$ 1AT gene to the cotton rat lung *in vivo* via intratracheal instillation.

Rosenfeld et al does not teach the deletion of the **entire** E1 region in their recombinant Adenoviral vector construct. Rather only a portion of the viral E1a coding sequence was deleted as evidenced at least in Figure 1 and at page 431, third column first full paragraph.

In contrast in the present invention the entire E1 region is deleted. Therefore, Applicants submit that the claims are not anticipated by Rosenfeld et al. and respectfully request withdrawal of this rejection.

**Rejection of Claims 10-16 Under 35 U.S.C. § 112, First Paragraph**

Claims 10 to 16 have been rejected under 35 U.S.C. § 112, first paragraph. In rendering this rejection, the Examiner purports that the specification is not enabled any non-replicative vector or any composition comprising that vector. Claim 10 to 14 and 16 have been canceled. As far as this rejection may pertain to the new Claims of record, Applicants submit that it has been obviated by the present amendment. More specifically, Claim 15 now recites a non replicative adenoviral vector with a heterologous polynucleotide inserted into a deleted E1 region of the vector.

In view of the above, withdrawal of this rejection is respectfully requested.

**Rejection of Claims 15, 16 Under 35 U.S.C. § 112, First Paragraph**

Claims 15 and 16 have been rejected under 35 U.S.C. § 112, first paragraph. In rendering this rejection the Examiner deems that this rejection is based upon the reading of the intended use language (for treatment of muscular diseases) into the claims. Claim 16 has been canceled. Claim 15 has been amended to delete this language rendering this rejection now moot. Therefore, withdrawal of the rejection is respectfully requested.

**Rejection Of Claims 15, 16 Under 35 U.S.C. § 112, Second Paragraph.**

Claims 15 and 16 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for reciting "for treatment of muscular diseases.". Claim 16 has been deleted and Claim 15 has been amended to delete this language thereby rendering this rejection now moot. Therefore withdrawal of the rejection is respectfully requested.

From the foregoing, favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.



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Respectfully submitted,

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